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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/943,144	10/03/97	KOSHIBA T	21850208P-SP

002292 HM22/0425
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EXAMINER	
ZAGHMOUT,O	
ART UNIT	**PAPER NUMBER**
1638	15

DATE MAILED: 04/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/943,144	Koshiba et al.
Examiner	**Group Art Unit**
Ousama Zaghmout	1638

☒ Responsive to communication(s) filed on *Feb 3, 2000* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *18-30* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *18, 19, and 22-30* is/are rejected.

☒ Claim(s) *20 and 21* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

STATUS OF APPLICATION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Status of the claims:

The amendment filed on 02/03/2000 has been received and entered (Paper No. 14).

Claim 21 has been amended [Paper No. 14].

Claims 18-30 are pending.

Claim Rejections - 35 U.S.C. § 112

1. Claims 18-19, 22-30 remain rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

A. Applicants argue that written description requirements have been satisfied since the specification teaches the size of the gene (4.4 kpb), the PCR primers as shown in SEQ ID: 7-15 and that the "Tm", PCR reactions and programs can be done without any undue

experimentation by those skilled in the art where the target gene can be separated on agarose gel electrophoresis (Remark section: paragraph 3, page 2; paragraph 1, page 3). Applicants' argument filed 2/3/00 have been carefully considered but not found to be persuasive for a number of reasons: First: The gene of 4.4 kpb (not 4.0 kpb as stated in Applicants' response) taught in the specification was isolated from corn, not of any other plant species. Second, the specification teaches primers which have sequences that are based on the nucleotide sequences of corn, not of any other plant species. The specification does not teach if the physical characteristics or the chemical property of nucleotide sequences from all plant species are the same as corn. Third: while the "Tm" value is critical in PCR reaction are so other parameters such as denaturation and extension. If these latter steps were not done properly according to the nucleotide sequence used in the PCR reactions, many false positive will be produced. If the primers were not correctly designed according to the sequence that is going to be isolated, then it will be like "a shot-gun" approach. Those skilled in the art would recognize that absent of these teachings from the specification that Applicants were not in possession of the invention as claimed at the time when the application was filed.

An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description

requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." Ralston Purina Co. v. Far-Mar-Co., Inc., 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

B. Applicants argue that specific written description is not needed and that a patent need not to teach , and preferably omits, what is well known in the art. In that respect, Applicants cite Spectra-Physics Inc. v. Coherent Inc as shown in paragraph 2, page 3 of the response. This is not found persuasive for a number of reasons: First: this information is not known in the art as discussed above. The nucleotide sequence encoding aldehyde oxidase is not known in the art from any plant species other than corn at the time when the application was filed. Second: the case law cited is misplaced as the nucleotide sequence encoding aldehyde oxidase from any plant species other than corn is not well-known in the art.

2. Claims 18-19 and 22-30 remain rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabled for isolation of sequences shown in SEQ ID NO:1-4, does not reasonably provide enablement for the isolation of an aldehyde oxidase gene

having a nucleotide sequence which encodes an amino acid sequence of a 4.4 Kbp gene obtainable from a plant using a combination of PCR primers that are selected from a group consisting of SEQ ID: 7-15 or for a process of controlling production of an aldehyde oxidase in transformed host cells which express nucleotide sequences isolated using said primers, for the reasons of record stated in the previous Office action.

A. Applicants argue that the present specification provides an enablement for the isolation of an aldehyde oxidase gene of 4.4 kbp. In that respect, Applicants argue that the specification teaches the size of the gene as a structural feature or physical property and primer sequences for a PCR reaction, and an assay of aldehyde oxidase activity as exemplified in Example 3 on pages 17-18, pages 6-7 of the present specification or in Koshiba et al reference (Plant Physiology. 1996, Vol. 110: 781-789) as described in page 6, lines 9-10 of the present specification (paragraph 3, page 4). Applicants further argue that the nucleotide sequence of aldehyde oxidase can be found by using a matching test of nucleotide sequence on the basis of the disclosed sequences. These arguments have been carefully considered but not found to be persuasive for a number of reasons: First: the specification disclosed only the sequences shown in SEQ ID: 1-4 which were isolated from corn. The specification does not teach sequences from other plant species which were isolated by a PCR reaction using said primers. Neither the specification nor the prior art teaches that the nucleotide sequence of aldehyde oxidase from corn can be successfully used to identify non-corn genes without undue experimentation. Those skilled in the art

would recognize that in order to be able to isolate a specific gene by a PCR reaction, a number of criteria should be known about the gene or the family of genes to be isolated such as identical sequences or conservative sequences. If none of these nucleotide sequences are known in the prior art at the time when the application was filed, then those skilled in the art have to go through trial and error to find which one works using the assay of aldehyde oxidase taught in the specification. Furthermore, those skilled in the art would recognize that prior to expression of a gene in an assay, the nucleotide sequence has to be identified, characterized from a number of plant species using large number of primers which covers a gene as big as 4.4 kpb; this is assuming genes from other plant species are 4.4 kpb and not bigger. Subsequently, this would amount to undue experimentation. This would be further complicated by the absence of the teaching from the specification of the conditions for the PCR reactions.

Applicants provide insufficient guidance as how to isolate, prepare, identify such materials other than a general indication to go look for it. In addition, claiming a genus of nucleic acid sequences may be achieved by means of a recitation of a representative number of DNA molecules, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features constitute a substantial portion of the genus. Thus, a specification based solely on the corn aldehyde oxidase gene could not enable and provide an adequate description for all such genes from any plant species. Therefore, the isolation and characterization of corn

aldehyde oxidase gene from one member of a genus (corn) is not sufficient to support or enable claims to that of thousands of other species of the genus.

Taken together, the instant disclosure lacks the proper and sufficient guidance to enable the claims as set forth. Thus it is not readily predictable that the genetic modification specifically disclosed will work with other plant species. Applicants have provided no specific guidance as to how to select the gene which encodes aldehyde oxidase from the PCR reaction that will give the desired fragments. One wishing to practice the invention is left to proceed through trial-and-error to see what will work and what will not. In view of the breadth of the claims, unpredictability of the art, lack of guidance in the specification of the results as stated above, it is the Examiner's position that one skilled in the art to which it pertains, or with which it is most nearly connected, could not practice the invention commensurate in scope with these claims without undue experimentations.

Conclusion

No claims are allowed.

Claims 20-21 are objected to.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-3724. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, L. Smith can be reached on (703) 308, 3909. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.
April 18, 2000

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~100~~ 1638